SAFETY ISSUES ASSOCIATED WITH
DIETARY SUPPLEMENT USE DURING PREGNANCY

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The FDA's regulation, issued under the 1994 Dietary Supplement Health and Education Act of 1994 (DSHEA), and put forth in final form on January 6th of this year, categorized "ordinary morning sickness" and "leg edema associated with pregnancy" as common conditions that are not "diseases." Under the dangerous provisions of DSHEA, that categorization allows dietary supplement manufacturers to promote products as treatments of those conditions without first proving that the products are safe and effective. We strongly disagree with that categorization.

Both morning sickness and edema of pregnancy, when uncomfortable enough to cause a woman to use a substance for relief of symptoms, are severe enough to be considered diseases. We urge you immediately to amend the rule explicitly to include morning sickness and edema of pregnancy as diseases. Although these are the only two pregnancy-related conditions which are explicitly mentioned, we are opposed to the idea that any claims for a pregnancy-related condition--be it structure/function or disease masquerading as non-disease such as nausea/vomiting or edema of pregnancy--be allowed to escape regulation as drugs. The exceptions, of course are vitamins (other than vitamin A supplements) and iron because there is actual evidence of deficiencies of these chemicals in pregnant women.

Moreover, morning sickness and edema of pregnancy and other problems associated with pregnancy, when severe enough to cause a woman to seek treatment, cannot be considered "normal." Rather, in that circumstance, the condition could very well be one that could cause "significant or permanent harm." For example, edema of pregnancy could well be an early symptom of pre-eclampsia or other types of toxemia of pregnancy which, if undiagnosed and not properly treated, can jeopardize the health of both the mother and infant. Morning sickness can progress to hyperemesis gravidarum (extreme and persistent vomiting) and severe dehydration and become life-threatening for mother and infant. Thus, even if pregnancy were properly categorized as a "life stage or process" comparable to adolescence or menopause--which it is not--these conditions would be diseases, under the FDA's own reasoning. See 65 Fed. Reg. 1020.

Even if the FDA decides, based on concerns about maternal and fetal harm, to disallow all pregnancy-related claims, this is not enough. Given that millions of Americans use herbals/dietary supplements, even in the absence of claims for treating problems of pregnancy, pregnant women may continue to use the supplements they started to use before they became pregnant. Thus, all supplements should be required to carry a warning "**DO NOT USE IF YOU ARE PREGNANT**" unless there is clear evidence from well conducted studies that there are no adverse reproductive effects.

Given that three such chemicals, caffeine, ephedra and vitamin A are known to cause birth defects or other adverse effects on reproduction and that few of the others have been tested, the combination of unknown reproductive toxicity and unknown benefit should serve to disallow their sale without the above pregnancy warning. A time limit should be placed for allowing the companies to conduct and submit to the FDA the reproductive toxicity studies necessary to determine these risks.

Since the generation of women who are now in the child-bearing age range are much more likely than their counterparts five or ten years ago to use the Internet as a source of information, it is instructive to look at the confusing, often conflicting information concerning herbals and pregnancy posted on the Web, usually by companies selling herbals/food supplements.

On one website is a list of herbals recommended for use by pregnant women. It includes such substances as black cohosh, blue cohosh (both to be used only during the third trimester), cleavers and horsetail. The company sponsoring this website is Snowbound Herbals. (Sbherbals.com/usefulin pregnancy.html)

On another website, information compiled by an RN and an Ob/Gyn discusses "Herbs to Avoid During Pregnancy and Breast Feeding." Among a list of herbals which are said to be too dangerous to use by pregnant women are several herbals also mentioned on the above list as recommended for use by pregnant women. These are "Black Cohosh: Can cause abortion. Diuretic"; "Blue Cohosh: Can cause abortion, induce contractions, diuretic"; "cleavers: Strong diuretic--not good for diabetics either"; "Horsetail: Diuretic, astringent".

Even more confusing is the fact that on another part of Snowbound Herbals website, under a section entitled "Herbs to Avoid in Pregnancy", two of the herbs to avoid, fennel "uterine stimulant, essential oils" and Lavender "essential oils and bitter principles" are ones recommended as "useful for pregnancy" on the above-mentioned portion of their website.

The cause of most birth defects remains unknown. The best evidence suggests that many birth defects are caused by agents that humans have consumed for hundreds of years. Although we do not have the evidence to identify which dietary supplements have been and continue to cause birth defects, it is reasonable to assume that humans are now consuming such agents. A government regulation that facilitates consumption by pregnant women of such agents, which have not been tested for their adverse effects on the fetus, will unfortunately put embryos and fetuses at risk.

In sharp contrast, chemicals that are classified as drugs must undergo rigorous scrutiny, before marketing approval, for any adverse effects on reproduction, including fetal toxicity and birth defects. As a result, data are available to allow such drugs to be categorized into one of several categories concerning risk of use during pregnancy. Currently, 81 drugs are listed in FDA Pregnancy Category X, defined as: **"Studies in animals or humans demonstrate fetal abnormalities or adverse reaction reports**

indicate evidence of fetal risk. The risk of use in a pregnant woman clearly outweighs any possible benefit." Included on this list are such chemicals as Vitamin A, ephedrine, and caffeine--all of which are found, not infrequently, in herbal preparations or dietary supplements. When sold as herbals or food supplements, these three chemicals sometimes, but not always, have a pregnancy warning. Because DSHEA does not allow the FDA to require the kinds of studies that would produce evidence to categorize other food supplements or herbals into safe or unsafe categories for use in pregnancy, claims for morning sickness or edema of pregnancy or any other pregnancy-related claims will be unaccompanied by any assurance that the products will not cause birth defects or other kinds of fetal toxicity.

In addition to the lack of meticulous evaluation of the safety and effectiveness of the ingredients which are supposed to be in these herbals/diet supplements, there is the additional problem with this dangerously under-regulated industry of contamination. In a study recently published in the New England Journal of Medicine (September 17, 1998, volume 239, page 847), scientists from the California Department of Health reported that 32% of 260 herbal products purchased off the shelves in California stores were contaminated with lead, arsenic or undeclared pharmaceuticals such as digitalis. Especially for the developing child, these toxic substances can be extremely dangerous.

The Presidential Executive Order of April 21, 1997, "Protecting Infants and Children from Environmental Health and Safety Hazards" speaks clearly to the recognition of the unique vulnerability of fetuses, infants and children. Because of its recognition of this heightened vulnerability to various chemicals, it requires all agencies of the federal government to take into account the unique vulnerabilities of infants and children in setting standards and issuing regulations.

Beyond this current battle concerning pregnancy-related conditions and labeling of all supplements against use in pregnancy is the larger issue of DSHEA itself. How many more people will have to be injured or killed by essentially unregulated dietary supplements such as ephedra and many others before DSHEA is significantly amended if not repealed. This law is a dangerous step back into the 19th century just as we are entering the 21st century.